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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,947	09/26/2003	Ming Hao Zheng	054756-5050US	9415

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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1657

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,947	ZHENG ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 11-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/04, 5/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response of 8/21/06 to a restriction requirement of 3/14/06 elected claims 1-10 without traverse.

Claims 11-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/21/06.

Claim examined on the merits are 1-10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear by reciting "adjacent to" in line 1 of claim 1. This language is unclear as to whether the stem cells are attached to the matrix or are merely beside the matrix and unattached. If the stem cells are not adhered to the matrix as in claim 10, the structure that forms the tissue repair structure is uncertain.

Claim 8 is confusing by requiring proteins or polypeptides to be selected from materials that are not proteins or polypeptides.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asculai et al (6,444,222 B1), and if necessary in view of Muller et al (6,623,963 B1).

The claims are drawn to a tissue repair structure comprising a cell-free support matrix and stem cells adjacent the matrix.

Asculai et al disclose a matrix membrane that can be used for transplantation of stem cells (col 3, line 65). The matrix can comprise type I and type III collagen, or type II collagen (col 12,

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lines 39-45). Cells are loaded on the matrix and the matrix implanted (paragraph bridging cols 6 and 7).

Muller et al disclose a collagen-based matrix that can be used as a scaffold for chondrocyte cells or stem cells (col 3, line 32).

5 It would have been obvious from Asculai et al to form a tissue repair structure comprising a matrix and stem cells as claimed since Asculai et al disclose a matrix for implanting that can be loaded with cells, which can be stem cells. If needed, Muller et al would have further suggested a matrix in combination with stem cells as claimed
10 from disclosing a matrix that can be used as a scaffold for implanting cells which can be stem cells. The conditions of the dependent claims would have been also obvious from Asculai et al since Asculai et al disclose that such conditions or similar conditions that can be used. As to claim 4, the cells of Asculai et al can be autologous, and it
15 would have been obvious to use collagen to prepare the matrix that is also autologous. Muller et al disclose that the cells can be allogenic (col 6, line 43), and the use of collagen that is also allogenic to form the matrix would have been obvious.

Claim Rejections - 35 USC § 103

20 Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asculai et al in view of Beretta et al (6,368,298 B1), and if necessary in view of Muller et al.

The claims require the matrix to be autologous and allogeneic, respectively.

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Beretta et al disclose preparing a solid-fibrin web that is autologous, which can be used to culture cells in vitro to obtain a graft for transplanting (col 5, lines 30-35).

It would have been obvious to substitute for the matrix of Asculai et al the solid-fibrin web of Beretta et al since the web is autologous. The web is inherently allogenic as in claim 5. Muller et al is applied, if needed, for the reason set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'DM. Naff', with a stylized flourish at the end.

David M. Naff
Primary Examiner
Art Unit 1651

DMN

11/13/06